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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/764,324	01/16/2001	Hui Wang	3262.1	7505

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EXAMINER

MORAN, MARJORIE A

ART UNIT PAPER NUMBER

1631

DATE MAILED: 02/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/764,324	Applicant(s) WANG ET AL.	
	Examiner Marjorie A. Moran	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 1-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. All objections and rejections not reiterated below are hereby withdrawn.

Drawings

New Figure 7 was received on 12/3/03. This drawing is acceptable to the examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

A step of selecting probes which target exemplar or target sequences for designing a probe array is new matter. Original claim 13 recited a preamble of "selecting sequences for designing a probe array", then recited steps of generating candidate design sequences. The original claims did not specifically recite which sequences were to be used to design a probe array, but given the preamble, claim 13 was interpreted to mean that the exemplar or consensus sequences generated were to be used for the purpose recited in the preamble. The original claims did not recite any limitation with regard to probes which target exemplar or consensus sequences, nor did the original claims recite using *probes* to design a probe array. In the response filed 12/3/03, applicant points to page 16 of the specification and Figure 5 for support

for the new limitation. Page 16 provides support for selecting either a consensus sequence or an exemplar sequence as a "candidate sequence", but fails to disclose any probes which target a consensus, exemplar, or other "candidate" sequence. Page 12 of the originally filed specification discloses that the "sequence selection process generates candidate sequences for probe selection." One skilled in the art could interpret this to mean that probes may be selected FROM the set of candidate sequences; i.e. the candidate sequences are themselves probes. There is no teaching anywhere in the originally filed specification which clearly and unambiguously discloses that probes (different from the candidate sequences) are to be selected which target exemplar or consensus sequences. There is no disclosure anywhere for using such probes to design a probe array. There is no description or example anywhere of probes which recognize or target exemplar or consensus sequences. As neither the originally filed specification or claims provide support for the newly filed limitations of claim 13, the claims are rejected for reciting new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 recites a step of selecting probes for designing a probe array, but does not recite where or from what set the probes are to be selected from. As one skilled in the art would not know the metes and bounds intended by applicant for the probes to be selected, the claims are indefinite.

Claim Rejections - 35 USC § 103

Applicant's arguments with respect to claims 13-18 have been considered but are moot in view of the new ground(s) of rejection set forth below.

Claims 13 and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over MILLER (Genome Research (Nov. 1999) volume 9 (11), pages 1143-1155) in view of RAMSAY, G. (IDS ref: Nature Biotech. (1/1998), vol. 16, pp. 40-44).

The claims are directed to a method of selecting a sequence wherein sequences are cleaned, clusters are refined, exemplar or consensus sequences are generated, and probes which target the exemplar or consensus sequences are selected. Claim 14 limits cleaning to removing withdrawn sequences, screening, filtering and masking raw sequences, and trimming terminal ambiguous sequences. Claim 15 limits refining clusters to two-level clustering. Claim 16 limits the method to generation of an exemplar sequence. Claim 17 limits generation to generating alignments, calling consensus sequence bases, and determining a consensus sequence direction. Claim 18 limits the determining of sequence direction to one wherein there is no contradictory sequence directions.

MILLER teaches a method of generating consensus/exemplar sequences wherein raw sequences are cleaned (masked), clusters are refined, and unique consensus sequences generated (p. 1145). MILLER teaches that his clustering is performed using the d2-algorithm, which is two-level clustering. MILLER also teaches that his consensus sequences are generated from clusters by base calling, and teaches that the direction of the consensus sequence may be determined. MILLER does not teach that his directional determination includes contradictory information (i.e. thus meeting the limitations of instant claim 18). MILLER teaches that tissue specific EST clusters may be used to map or screen for genes or chromosomal regions implicated in diseases, and teaches that his consensus sequence clusters

may be used as a source for gene discovery (p. 1154). MILLER does not specifically teach selecting probes specific for consensus sequences.

RAMSAY teaches generation of probe arrays and their use in discovering genes involved in disease (p. 42). RAMSAY specifically teaches that clustered sequences may be analyzed according to probes which target them, and that the probes may be used in gene screening (p. 42).

It would have been obvious to one of ordinary skill in the art at the time of invention to have selected probes target clustered or consensus sequences, as taught by RAMSAY, in the method of MILLER, where the motivation would have been to selected probes for use in screening for gene expression, identifying genes associated with diseases, etc., as taught by RAMSAY and suggested by MILLER.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over MILLER (Genome Research (Nov. 1999) volume 9 (11), pages 1143-1155) in view of RAMSAY, G. (IDS ref: Nature Biotech. (1/1998), vol. 16, pp. 40-44) as applied to claims 13 and 15-18 above, and further in view of BURKE et al. (IDS ref: Genome Research (1999) volume 9, pages 1135-1142).

The claims are directed to a method of selecting a sequence wherein sequences are cleaned, clusters are refined, exemplar or consensus sequences are generated, and probes are selected, as set forth above. Claim 14 limits cleaning to removing withdrawn sequences, screening, filtering and masking raw sequences, and trimming terminal ambiguous sequences.

MILLER and RAMSAY make obvious a method of generating consensus sequences and selecting probes which target them, as set forth above. MILLER teaches removing withdrawn sequences, screening/filtering/masking raw sequences, and teaches removal of repeat

sequences and vector sequences (p. 1145), but does not specifically teach trimming or removing ambiguous terminal sequences.

BURKE teaches removing various 3' sequences when forming clusters (p. 1136).

It would have been obvious to one of ordinary skill in the art at the time of invention to have removed "ambiguous" or any other problem sequences from the termini of sequences (e.g. 3' sequences), as taught by BURKE, before clustering in the method of MILLER and RAMSAY, where the motivation would have been to improve accuracy of the clustering, as suggested by MILLER's teaching for removal of repetitive and vector sequences.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

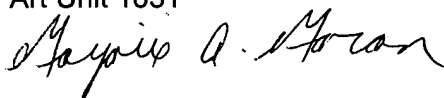
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571) 272-0720. The examiner can normally be reached on Mon. to Wed, 7:30-4; Thurs 7:30-6; Fri 7-1 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571)272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marjorie A. Moran
Primary Examiner
Art Unit 1631



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